REMARKS

In the Office Action dated March 2, 2006, claims 1, 8-10, 16-18, 24-26, 30-32, 36-38, 49, 51, 52 and 55-58 are allowed. Claims 46, 47, 53 and 54 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Claims 11, 14, 15, 19, 22, 23, 27, 33, 39, 42, 46, 47, 53 and 54 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 11, 14, 15, 19, 22, 23, 27, 33, 39 and 42-45 are rejected under 35 U.S.C. § 112, first paragraph, as being allegedly non-enabling. Claims 11, 14, 15, 19, 22, 23, 27, 33, 39 and 42 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Daniell (U.S. Patent Application Publication No. 2003/0041353; "*Daniell*") in view of each of Johnson *et al.* (1989, *Proc. Natl. Acad. Sci. USA* 86:9871-9875; "*Johnson*") and Graham *et al.* (1985, *J. Biol. Chem.* 260:6561-6564; "*Graham*"). Claims 2, 4-7 and 48 are herein cancelled as being non-elected claims. Claims 11, 19, 27, 33 and 39 are herein cancelled without prejudice. Claims 14, 22 and 42 are herein amended to depend only from allowed claims. No new matter has been introduced. Claims 1, 8-10, 14-18, 22-26, 30-32, 36-38, 42-47, 49 and 51-58 are pending in the case.

Reconsideration of the present application in view of the foregoing amendments and remarks below is respectfully requested.

Claim Rejection under 35 U.S.C. § 112

(1) Claims 46, 47, 53 and 54 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Specifically, the Office Action states that the deposits of pSa7 and pML VHisA under the Budapest Treaty are not persuasive because no affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and

registration number, stating that strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

A statement of the undersigned, an attorney of record, under 37 C.F.R. § 1.808(a) and (b), is attached hereto.

Accordingly, the rejection of claims 46, 47, 53 and 54 under 35 U.S.C. § 112, first paragraph, as being non-enabling, should be withdrawn.

(2) Claims 11, 14, 15, 19, 22, 23, 27, 33, 39, 42-47, 53 and 54 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

With regard to claims 11, 14, 15, 19, 22, 23, 27, 33, 39 and 42-45, the Office Action states that "[a]pplicant does not describe an isolated nucleic acid molecule having a nucleotide sequence that hybridizes to SEQ ID NO:1, wherein the nucleotide sequence encodes a protein having proteinase inhibitor activity" and that "the genus of proteinase-inhibitor encoding nucleic acids that hybridize to SEQ ID NO:1 is very broad, and includes nucleic acids that hybridize to only a small portion of SEQ ID NO:1; thus, SEQ ID NO:1 is not sufficient to represent their sequences." The Office Action further states that "[t]he only species described in the specification are SEQ ID NO:1 and 3. These species do not describe the full scope of this very broad genus."

Applicants respectfully traverse the rejection for the reasons presented in the response filed December 14, 2005, which is hereby incorporated by reference in its entirety.

As the Examiner acknowledges, SEQ ID NO:1 and 3 are the two (2) species disclosed that are within the scope of the claimed genus, *i.e.*, "a nucleotide sequence that hybridizes under stringent conditions to the complement of the nucleotide sequence

of SEQ ID NO:1" and that "encodes a protein having proteinase inhibitor II activity" as recited in claims 11, 19, 27, 33 and 39. The "Synopsis of Application of Written Description Guidelines ('Guidelines')" provided by the United States Patent and Trademark Office ("USPTO"), shows an example (Example 9) in which the claim is drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO:1 and must encode a protein with a specific activity. In the specification, a single species (a molecule consisting of SEQ ID NO:1) that is within the scope of the claimed genus is disclosed. The Guidelines states that "the art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing" and the disclosure of a single species is said to be "actual reduction to practice of the disclosed species". In support of this view, Applicants submitted previously, for the Examiner's reference, a copy of Sambrook, Chapter 8 (please see pages 8.46-8.49) as well as a copy of Instruction Manual of Hybond-N by Amersham Biosciences, both of which teach hybridization techniques.

Furthermore, the Guidelines states at pp. 36-37 as follows:

> Now turning to the genus analysis, ***a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs***. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention. (emphasis added).

Thus, the Guidelines conclude that "[t]he claimed invention is adequately described."

The present application has a similar situation as that of Example 9 of the Guidelines. And the present application discloses at least two (2) sequences (*i.e.*, SEQ

ID NOS: 1 and 3) that hybridize under the stringent condition as recited in the rejected claims to the complement of SEQ ID NO:1 and, therefore, "a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention."

Thus, the present specification fully complies with the written description requirement under 35 U.S.C. § 112, first paragraph, with regard to claims 11, 14, 15, 19, 22, 23, 27, 33 39 and 42-45.

However, in order to solely accelerate the prosecution of the present application, claims 11, 19, 27, 33 and 39 are herein cancelled. Applicants expressly reserve a right to pursue the cancelled claims in a continuation application.

Claims 14, 22 and 42 are herein amended to depend only from the allowed claims.

With regard to claims 46, 47, 53 and 54, Applicants believe that the statement under 37 C.F.R. § 1.808(a) and (b) that is concurrently submitted herewith should overcome the rejection.

Accordingly, Applicants respectfully request that the rejection of claims 14, 15, 22, 23, 42-47, 53 and 54 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, be withdrawn.

(3) Claims 11, 14, 15, 19, 22, 23, 27, 33, 39 and 42-45 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

In summary, the Office Action states that "[t]he instant specification fails to provide guidance for proteinase-inhibitor encoding nucleic acids that hybridize to SEQ ID NO:1 or for methods of transformation of lettuce plastids.

Applicants respectfully traverse the rejection.

As discussed in the previous section, the "Guidelines" states that "the art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing" and that "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs." The methods for expressing thus-isolated nucleic acids are described in detail in Sections 5.1 and 5.3-5.8 of the present specification and the method for detecting trypsin and chymotrypsin inhibitory activity is described at page 42 of the specification. In combination with the level of the ordinary skilled in the art, the methods recited in the rejected claims are enabling without undue experiments.

Nevertheless, claims 11, 19, 27, 33 and 39 are herein cancelled without prejudice to solely accelerate the prosecution of the present application and, therefore, the rejection of these claims are now moot.

Claims 14, 22 and 42 are herein amended to depend only from the allowed claims and are enabling.

Accordingly, the rejection of claims 11, 14, 15, 19, 22, 23, 27, 33, 39 and 42-45 under 35 U.S.C. § 112, first paragraph, as lacking enablement, should be withdrawn.

Claim Rejection under 35 U.S.C. § 103

Claims 11, 14, 15, 19, 22, 23, 27, 33, 39 and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Daniell* in view of each of *Johnson* and *Graham*.

Applicants respectfully traverse the rejection.

The objective of *Daniell* is to express polycistronic genes via the plastid genome in a single transformation event and, as the Office Action acknowledges, *Daniell* does not teach or even suggest anything about transforming plant plastids with proteinase-inhibitor encoding nucleic acids. *Johnson* discloses ***nuclear transformation*** of tobacco plants using TI-II DNA, of which tomato leaf inhibitor II is disclosed by *Graham*. Neither *Johnson* nor *Graham* discloses anything about plastid transformation of TI-II DNA and, in fact, *Johnson* discloses that "the introns of both inhibitor I and inhibitor II genes were correctly excised and that pre and prepro inhibitor I and II proteins were correctly processed" using nuclear transformation (see Abstract of *Johnson*). Thus, there is no motivation for one skilled in the art to combine *Daniell*, *Johnson* and *Graham* and to devise a method for plastid transformation of plants with TI-II DNA and the present claims are not obvious over *Daniell* in view of each of *Johnson* and *Graham*.

Nevertheless, claims 11, 19, 27, 33 and 39 are herein cancelled as discussed above and, therefore, the rejection of these claims is now moot.

Claims 14, 22 and 42 are herein amended to depend only from the allowed claims and are enabling.

Accordingly, the rejection of claims 11, 14, 15, 19, 22, 23, 27, 33, 39 and 42 under 35 U.S.C. § 103(a) as being unpatentable over *Daniell* in view of each of *Johnson* and *Graham*. should be withdrawn.

In view of the above amendments, Applicants believe that the pending claims are now in condition for allowance, an early notification of which is earnestly requested.

No fee is believed to be due for this Amendment. Should any fees be required, please charge such fees to Deposit Account No. 50-2215.

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Respectfully submitted,

By _____

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Attachment: Statement under 37 C.F.R. § 1.804(a) and (b).